

IN THE CLAIMS

This listing of claims replaces all prior versions, and listings, in this application.

1. (currently amended) A controlled-release pharmaceutical composition, comprising:

- 1) a core containing an acid-unstable physiologically active substance, a disintegrant, and an alkaline additive and
- 2) a release-controlling coating which covers the core, and which contains a water-insoluble polymer, an enteric polymer, and a hydrophobic wax;

wherein the enteric polymer is at least one selected from the group consisting of hydroxypropyl methyl cellulose phthalate, hydroxypropyl methyl cellulose acetate succinate, a methacrylic acid-methyl methacrylate copolymer (Eudragit L, Eudragit S), and a methacrylic acid-ethyl acrylate copolymer (Eudragit LD);
wherein the hydrophobic wax is at least one selected from the group consisting of magnesium stearate, calcium stearate, stearic acid, carnauba wax, and a hydrogenated oil; and

wherein the hydrophobic wax is 20 to 35 wt%, based on the weight of the release-controlling coating.

2. (original) The controlled-release pharmaceutical composition according to claim 1, wherein the release-controlling coating further comprises a plasticizer.

Claim 3 (canceled)

4. (previously presented) The controlled-release pharmaceutical composition according to claim 1, further comprising an inert intermediate coating between the core and the release-controlling coating.

5. (previously presented) The controlled-release pharmaceutical composition according to claim 1, wherein the controlled-release pharmaceutical composition is a pulsed-release pharmaceutical composition.

6. (previously presented) The controlled-release pharmaceutical composition according to claim 1, wherein the disintegrant is at least one selected from the group consisting of crospovidone, low-substituted hydroxypropyl cellulose, croscarmellose sodium, and carmellose calcium.

7. (previously presented) The controlled-release pharmaceutical composition according to claim 1, wherein the water-insoluble polymer is at least one selected from the group consisting of ethyl cellulose, an aminoalkyl methacrylate copolymer RS (Eudragit RS), and shellac.

Claims 8-9 (canceled)

10. (previously presented) The controlled-release pharmaceutical composition according to claim 1, wherein the water-insoluble polymer is ethyl cellulose, the enteric polymer is a methacrylic acid-methyl methacrylate copolymer (Eudragit L, Eudragit S), and the hydrophobic wax is magnesium stearate or calcium stearate.

11. (previously presented) The controlled-release pharmaceutical composition according to claim 2, wherein the plasticizer is at least one selected from the group consisting of triethyl citrate, cetyl alcohol, glycerol fatty acid ester, and propylene glycol.

12. (previously presented) The controlled-release pharmaceutical composition according to claim 1, wherein the amount of the water-insoluble polymer and the enteric polymer in the release-controlling coating is 40 to 90 wt%, based on the weight of the release-controlling coating.

Claim 13 (canceled)

14. (previously presented) The controlled-release pharmaceutical composition according to claim 1, wherein the amount of the water-insoluble polymer in the release-controlling coating is 3.0 to 95 wt%, based on the total amount of the water-insoluble polymer and the enteric polymer in the release-controlling coating.

15. (previously presented) The controlled-release pharmaceutical composition according to claim 2, wherein the amount of the plasticizer in the release-controlling coating is 0.1 to 20 wt%, based on the weight of the release-controlling coating.

16. (previously presented) The controlled-release pharmaceutical composition according to claim 1, wherein the acid-unstable physiologically active substance is a benzimidazole-based compound or a physiologically acceptable salt thereof.

17. (original) The controlled-release pharmaceutical composition according to claim 16, wherein the benzimidazole-based compound or physiologically acceptable salt thereof is rabeprazole, omeprazole, pantoprazole, lansoprazole or esomeprazole, or a physiologically acceptable salt thereof.

18. (previously presented) The controlled-release pharmaceutical composition according to claim 16, wherein the benzimidazole-based compound or physiologically acceptable salt thereof is rabeprazole sodium.

19. (previously presented) The controlled-release pharmaceutical composition according to claim 1, wherein the alkaline additive is at least one selected from the group consisting of sodium hydroxide, potassium hydroxide, magnesium oxide, calcium oxide, magnesium hydroxide, and calcium hydroxide.

20. (previously presented) The controlled-release pharmaceutical composition according to claim 1, wherein the controlled-release pharmaceutical composition is a tablet, a granular preparation, or a fine granular preparation.

21. (previously presented) A capsule preparation, comprising:

- 1) the controlled-release pharmaceutical composition according to claim 1 and
- 2) an enteric pharmaceutical composition in which a core containing an acid-unstable physiologically active substance is covered with an enteric coating.

22. (previously presented) A packaging container, comprising:

- 1) the controlled-release pharmaceutical composition according to claim 1 and
- 2) an enteric pharmaceutical composition in which a core containing an acid-unstable physiologically active substance is covered with an enteric coating,

wherein both of the compositions are present in the same packaging container.

23. (previously presented) A packaging container, which contains a package comprising: the capsule preparation according to claim 21.

24. (previously presented) The container according to claim 22, wherein the packaging container is sachet or blister packaging.

25. (withdrawn-currently amended) A method for producing a controlled-release pharmaceutical composition comprising: forming a release-controlling coating by spraying a solution containing a mixture of a water-insoluble polymer, an enteric polymer and a hydrophobic wax onto a core containing an acid-unstable physiologically active substance, a disintegrant, and an alkaline additive to form a coating covering the core;

wherein the enteric polymer is at least one selected from the group consisting of hydroxypropyl methyl cellulose phthalate, hydroxypropyl methyl cellulose acetate succinate, a methacrylic acid-methyl methacrylate copolymer (Eudragit L, Eudragit S), and a methacrylic acid-ethyl acrylate copolymer (Eudragit LD);

wherein the hydrophobic wax is at least one selected from the group consisting of magnesium stearate, calcium stearate, stearic acid, carnauba wax, and a hydrogenated oil; and

wherein the hydrophobic wax is 20 to 35 wt%, based on the weight of the release-controlling coating.

26. (withdrawn) The method for producing a controlled-release pharmaceutical composition according to claim 25, wherein the release-controlling coating further comprises a plasticizer.

Claim 27 (canceled)

28. (withdrawn) The method for producing a controlled-release pharmaceutical composition according to claim 25, further comprising forming an inert intermediate coating between the core and the release-controlling coating.

29. (withdrawn) The method for producing a controlled-release pharmaceutical composition according to claim 25, wherein the controlled-release pharmaceutical composition is a pulsed-release pharmaceutical composition.

30. (withdrawn-currently amended) A method of controlling release to reduce variation in a dissolution lag time, comprising: covering a core containing an acid-unstable physiologically active substance, a disintegrant, and an alkaline additive with a release-controlling coating containing a water-insoluble polymer, an enteric polymer, and a hydrophobic wax;

wherein the enteric polymer is at least one selected from the group consisting of hydroxypropyl methyl cellulose phthalate, hydroxypropyl methyl cellulose acetate succinate, a methacrylic acid-methyl methacrylate copolymer (Eudragit L, Eudragit S), and a methacrylic acid-ethyl acrylate copolymer (Eudragit LD);

wherein the hydrophobic wax is at least one selected from the group consisting of magnesium stearate, calcium stearate, stearic acid, carnauba wax, and a hydrogenated oil; and

wherein the hydrophobic wax is 20 to 35 wt%, based on the weight of the release-controlling coating.